

Docket No.:

CI-0013



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of :  
Wilson BURGESS et al. : Group Art Unit: 1636  
Serial No.: 10/024,043 : Examiner: Not yet assigned  
Filed: December 21, 2001 :  
For: METHODS OF STERILIZING :  
HEART VALVES :  
:

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- 1. This Information Disclosure Statement is being filed (i) within three months of the U.S. filing date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
- 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
  - a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X c. Attached is our check no. 3215 in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no.        in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
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- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- X 4. The relevancy of the non-English language references can be determined from the attached abstracts.
- X 5. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
FLESHNER & KIM, LLP



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Date: April 5, 2002

MLF:DRM:kpc

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**LIST OF PRIOR ART CITED BY  
APPLICANT**

(PTO-1449)

ATTY. DOCKET NO. <b>CI-0013</b>	APPLN. SERIAL NO. <b>10/024,043</b>
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APPLICANT <b>Wilson BURGESS et al.</b>
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FILING DATE <b>December 21, 2001</b>	GROUP <b>1636</b>
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**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
VJF	RE 23,195	02/1950	Arno Brasch			
↑	2,832,689	04/1958	Bernard E. Proctor et al.			
	2,920,969	01/1960	E.S. Stoddard			
	2,962,380	11/1960	J.H. Wertheim			
	3,620,944	11/1971	Keiko Tanito			
	3,743,480	07/1973	John D. Falk			
	3,779,706	12/1973	Nablo			
	4,136,094	01/1979	Condie			
	4,251,437	02/1981	Rasmussen et al.			
↓	4,282,863	08/1981	Beigler et al.			
VJF	4,330,626	05/1982	Blair et al.			

**U.S. PATENT APPLICATION PUBLICATIONS**

	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	

**U.S. PATENT APPLICATIONS**

	*APPLN. NO.	*FILING DATE	*INVENTOR	CLASS	SUBCLASS	

**FOREIGN PATENT DOCUMENTS**

EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
						Yes	No
VJF	2,056,619	10/1991	Canada				
	310 316	04/1989	Europe				
	334 679	09/1989	Europe				
	919 918 A2	06/1999	Europe (Abstract)			X	
VJF	919 918 A3	06/1999	Europe (Abstract)			X	

**OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)**

AABB FDA Liaison Meeting, ABC Newsletter, December 12, 1997, pp. 14
Ozan Akkus et al., Fracture Resistance of Gamma Radiation Sterilized Cortical Bone Allografts, 2001, pps. 927-934, Journal of Orthopaedic Research, Vol. 19
Tikvah Alper et al., The Exceptionally Small Size of the Scrapie Agent, 1966, pps. 278-284, Biochemical and Biophysical Research Communications, Vol. 22, No. 3

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<b>LIST OF PRIOR ART CITED BY APPLICANT</b> <small>O I P E C S C R I P T APR 05 2002 (PTO-1449)</small>				ATTY. DOCKET NO. <b>CI-0013</b>	APPLN. SERIAL NO. <b>10/024,043</b>	
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<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
V A	4,370,264	01/1983	Kotitschke et al.			
A	4,409,105	10/1983	Hayashi et al.			
	4,472,840	09/1984	Jefferies			
	4,620,908	11/1986	Van Duzer			
	4,865,602	09/1989	Smestad et al.			
	4,933,145	06/1990	Uchida et al.			
	4,946,648	08/1990	Dichtelmüller et al.			
	4,963,356	10/1990	Calenoff et al.			
	5,000,951	03/1991	Bass et al.			
	5,106,619	04/1992	Wiesehahn et al.			
	5,134,295	07/1992	Wälischmiller			
V A	5,185,371	02/1993	Rubinstein			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation
V A	11-216147	08/1999	Japan (Abstract)			Yes X No
	1321420-A	07/1987	Soviet Union (Abstract)			X
	WO 90/00907	02/1990	PCT Int'l (Abstract)			X
V	WO 91/16060	10/1991	PCT Int'l (Abstract)			X
V A	WO 95/03071	02/1995	PCT Int'l (Abstract)			X
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses						
Irradiated as Dry Preparations, 1968, pps. 157-166, J. Gen. Virol., Vol. 3						
Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214						
Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. Gen. Virol., Vol. 41						
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<b>U.S. PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
V/A	5,226,065	07/1993	Held et al.			
	5,362,442	11/1994	Kent			
	5,418,130	05/1995	Plat. et al.			
	5,460,962	10/1995	Kemp			
	5,510,122	04/1996	Sreebny et al.			
	5,603,894	02/1997	Aikus et al.			
	5,609,864	03/1997	Shanbrom			
	5,637,451	06/1997	Ben-Hur et al.			
	5,643,464	07/1997	Rhee et al.			
	5,712,086	01/1998	Horowitz et al.			
↓	5,730,933	03/1998	Peterson			
V/A	5,817,528	10/1998	Böhm et al.			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
	*PATENT APPLN. PUB. NO.	*PUB. DATE	*APPLICANT	CLASS	SUBCLASS	
<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation
V/A	WO 00/25839	03/2000	PCT Int'l (Abstract)			X
↑	WO 01/08611A1	02/2001	PCT Int'l (Abstract)			X
	WO 01/12318A1	02/2001	PCT Int'l (Abstract)			X
↓	WO 01/32107A2	05/2001	PCT Int'l (Abstract)			X
V/A	WO 01/32110A2	05/2001	PCT Int'l (Abstract)			X
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
	S.R. Aparicio et al., Light and Electron Microscopy Studies on Homograft and Heterograft Heart Valves, 1975, pps. 174-162, J. Path, Vol. 115					
	J. Baksa et al., The Use of Pig's Skin (xenograft) for the Treatment of Burns, 1976, pps. 138-145, Magyar Traumatologin, Vol. 19					
	Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 10-78, American Association of Blood Banks					
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<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	TRADEMARK QUIT	*PATENT NO.	*ISSUE DATE	*INVENTOR NAME	CLASS	SUBCLASS	FILING DATE
VJ		5,837,313	11/1998	Ding et al.			
JJ		5,881,534	03/1999	Ahlqvist et al.			
		5,981,163	11/1999	Horowitz et al.			
		5,986,168	11/1999	Noishiki			
		6,046,024	04/2000	Burton et al.			
		6,049,025	04/2000	Stone et al.			
		6,066,626	05/2000	Yew et al.			
		6,087,141	07/2000	Margolis-Nunno et al.			
		6,120,592	09/2000	Brault et al.			
		6,159,490	12/2000	Deghenghi			
VJ		6,171,549	01/2001	Kent			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>							
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<b>FOREIGN PATENT DOCUMENTS</b>							
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
VJ	WO 01/45720A1	06/2001	PCT Int'l (Abstract)			X	
JJ	WO 01/49219A1	07/2001	PCT Int'l (Abstract)			X	
	WO 01/72233A1	10/2001	PCT Int'l (Abstract)			X	
V	WO 01/72244A1	10/2001	PCT Int'l (Abstract)			X	
VJ	WO 01/91818A1	12/2001	PCT Int'l (Abstract)			X	
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>							
	R.H. Bassin et al., Abrogation of Fv-1 <sup>b</sup> Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2						
	Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150						
	Sandra Blakeslee, Tight Rules on Use of Organs Do Not Apply to Tissues, January 20, 2002,						
	The New York Times Newspaper						
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LH	6,187,572	02/2001	Platz et al.			
A	6,190,855	02/2001	Herman et al.			
	6,197,207	03/2001	Chapman et al.			
	6,203,544	03/2001	Gotzen			
	6,214,534	04/2001	Horowitz et al.			
	6,235,508	05/2001	Sowemimo-Coker et al.			
	4,784,850	11/1998	Abraham			
	4,798,611	01/1989	Freeman, Jr.			
	5,283,034	02/1994	Okrongly et al.			
LP	5,548,066	08/1996	Leneau et al.			
LP	5,989,498	11/1999	Odland			
<b>U.S. PATENT APPLICATION PUBLICATIONS</b>						
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<b>FOREIGN PATENT DOCUMENTS</b>						
EXAMINER'S INITIALS	PATENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	Translation <input type="checkbox"/> Yes <input type="checkbox"/> No
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.)</b>						
	Seymour S. Block, Disinfection, Sterilization, and Preservation, Fundamental Principles of Activity					
	Principles of Antimicrobial Activity, Fourth Edition, 1991, pps. 31-33					
	A.J.J.C. Bogers et al., Long-Term Results of the Gamma-Irradiation-Preserved Homograft Monocusp for Transannular Reconstruction of the Right-Ventricular Outflow Tract in Tetralogy of Fallot, 1994, pps. 337-330, Thorac. Cardiovasc. Surgeon, Vol. 42					
	David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001 pps. 69-76, Journal of Neurochemistry, Vol. 76					
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<p>P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102</p> <p>P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39</p> <p>Paul Brown et al., Effect of Chemicals, Heat, and Histopathologic Processing on High-Infectivity Hamster-Adapted Scrapie Virus, May 1982, pps. 683-687, The Journal of Infectious Diseases, Vol. 145, No. 5</p> <p>P. Brown et al., The Distribution of Infectivity in Blood Components and Plasma Derivatives in Experimental Models of Transmissible Spongiform Encephalopathy, September 1998, pps. 810-816, Transfusion, Vol. 38</p> <p>D.G. Campbell et al., Sterilization of HIV With Irradiation: Relevance to Infected Bone Allografts, 1999, pps. 517-521, Aust. N.Z.J. Surg., Vol. 69</p> <p>Ernest U. Conrad et al., Transmission of the Hepatitis-C Virus by Tissue Transplantation, February 1995, pps. 214-224, The Journal of Bone and Joint Surgery, Vol. 77-A, No. 2</p> <p>A.S. Dagli, Correction of Saddle Nose Deformities by Coral Implantation, 1997, pps. 274-276, Eur. Arch. Otorhinolaryngol, Vol. 254</p> <p>Defeng et al., Sterilization of Silver-Acidum Pipemicidum Skin for the Treatment of Burns by Radioactive Cobalt-60-Gamma-Ray, 1995, pps. 406 (Abstract)</p> <p>P. Di Simplicio et al., The Reactivity of the SH Group of Bovine Serum Albumin With Free Radicals, 1991, pps. 253-262, Free Rad. Res. Comms., Vol. 14, No. 4</p> <p>R.J. Donnelly et al., Gamma-radiation of Heart Valves at 4°C; A Comparative Study Using Techniques of Histochemistry and Electron and Light Microscopy, 1973, pps. 95-101, Thorax, Vol. 28</p> <p>Duane C. Eichler et al., Radiation Inactivation Analysis of Enzymes, July 15, 1987, pps. 9433-9436, The Journal of Biological Chemistry, Vol. 262, No. 20</p> <p>Luanne H. Elliott et al., Inactivation of Lassa, Marburg and Ebola Viruses by Gamma Irradiation, Oct. 1982, pps. 704-708, Journal of Clinical Microbiology, Vol. 16, No. 4</p> <p>Bradley M. Fideler et al., Gamma Irradiation: Effects on Biomechanical Properties of Human Bone-Patellar Tendon-Bone Allografts, 1995, pps. 643-646, American Journal of Sports Medicine, Vol. 23, No. 5</p> <p>Bradley M. Fideler et al., Effects of Gamma Irradiation on the Human Immunodeficiency Virus, July 1994, The Journal of Bone and Joint Surgery, Vol. 76-A, No. 7</p> <p>Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222</p> <p>J.R.P. Gibbons et al., Effects of Gamma Irradiation on the Initial Mechanical and Material Properties of Goat Bone-Patellar Tendon-Bone Allografts, 1991, pps. 209-218, J. Orthop Res, Vol. 9, No. 2</p>		
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